K100739
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510(k) Summary

DEC - 7 2010

Submitter:	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614-5686
Contact Person:	Patricia A. Milbank Vice President, RA/CA
Date Prepared:	November 29, 2010
Trade name:	VolumeView System
Classification Name:	Probe, Thermodilution (21 CFR 870.1915) Catheter Guidewire (21 CFR 870.1330)
Predicate Devices:	Catheter: Pulsion Pulsiocath Thermodilution Catheters & Accessories; cleared under K072364 Manifold: Pulsion Pulsiocath Thermodilution Catheters & Accessories; cleared under K072364 Guidewire: Lake Region Mfg. Guidewire, cleared under K935170
Device Description:	The VolumeView System consists of a 4 or 5 French, 16 or 20 cm, two lumen femoral artery catheter and a CVC thermistor manifold. One catheter lumen has a thermistor for making blood temperature measurements, and the other is used for pressure monitoring. The manifold is used for injecting thermodilution boli through a central venous catheter. The guidewire is a PTFE-coated nitinol guidewire.
Intended Use:	The VolumeView system is indicated for use in critical care patients in which cardio-respiratory function, fluid status, and vascular resistance need constant and/or intermittent assessment. The femoral arterial catheter is indicated for femoral artery insertion.
Comparative Analysis:	The VolumeView System has been demonstrated to be as safe and effective as the predicate devices for their intended use.
Functional/Safety Testing:	The VolumeView System has successfully undergone functional testing. This product has been shown to be equivalent to the predicate devices.
Conclusion:	The proposed VolumeView System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Edwards Lifesciences, LLC
c/o Ms. Patricia Milbank, J.D.
Vice President, RA/CA, Critical Care
One Edwards Way
Irvine, CA 92614

DEC - 7 2010

Re: K100739
Trade/Device Name: VolumeView System
Regulatory Number: 21 CFR 870.1915
Regulation Name: Thermodilution Probe
Regulatory Class: II (two)
Product Code: KRB
Dated: November 19, 2010
Received: November 22, 2010

Dear Ms. Milbank:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K100739

Indications for Use Statement

510(k) Number (if known): K100739

Device Name: VolumeView System

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Indications for Use:

The VolumeView system is indicated for use in critical care patients in which cardio-respiratory function, fluid status, and vascular resistance need constant and/or intermittent assessment. The femoral arterial catheter is indicated for femoral artery insertion.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vickers

(Division Sign-Off)
Division of Cardiovascular Devices

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